Monday Morning Practice Pearls #12

So you submitted an expedited adverse event (AE) report - now what?

There is a subset of AEs that need to be reported more quickly to regulatory groups (i.e., sooner than routine data submissions, continuing reviews, or annual reports). This reporting includes new and unexpected AEs that impact safety (i.e., risk) and may lead to a revision in the protocol, investigator brochure, and/or informed consent. The AE data submitted for on these reports must also be captured on the routine AE case report form (CRF), which for many of you is C3D.

The following AE information should be the same on the AE CRF as on the expedited AE form, for each applicable AE:

- Start date
- AE term
- Grade
- Attribution
- Stop date, if applicable.

Since the forms are generally completed by 2 different members of the research team (i.e., the research nurse completes the expedited form whereas the data manager completes the CRF), it is important to ensure the data is the same.

The research nurse should perform a quality assurance (QA) check on the 2 "forms" (i.e., verify this data). If this is done, there should be no discrepancies or queries generated due to conflicting data.

Below are some tips to stay on top of this QA activity:

- Ensure that documentation about the expedited AE is in CRIS
- Share all expedited AE report forms with your data manager
- QA check the AE data to ensure the same data is on the routine "form" and the expedited "form"

For CTEP studies:

There is an AdEERS-CDUS reconciliation process to ensure that the events reported to the AE Expedited Reporting System (AdEERS) and those reported to the routine reporting system (CDUS from C3D for CCR) match. Discrepancies may occur if:

- Different Patient IDs in the two systems
- Different events, grades, or attributions in the two systems
- Complete lack of a reported event in one of the systems.

AE discrepancies that are considered lower priority, as defined by CTEP, result in a *Caution error/report* when data is submitted to CDUS. CTEP expects that these will be reviewed by the submitting site and corrected. Some of the cautions may fall into the last bullet above. CTEP has programmed into CDUS what AEs should be reported via AdEERS based on the SPEER (Specific Protocol Exceptions to Expedited Reporting) but your protocol may have further exceptions. You still should review the report to make sure that you didn't miss a submission, but if in fact you don't need to submit, you don't need to do anything further.